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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/744,658 | 05/30/2001 | Barbara P. Wallner | 10248/7014 | 3397 |
| 7590 08/12/2004 | | | EXAMINER | |
| Elizabeth R Plumer Wolf Greenfield & Sacks Federal Reserve Plaza 600 Atlantic Avenue Boston, MA 02210-2211 | | | RUSSEL, JEFFREY E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/744,658

Applicant(s)

WALLNER, BARBARA P.

Examiner

Jeffrey E. Russel

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1, 7-12 and 14-16.

Claim(s) withdrawn from consideration: 22 and 23.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

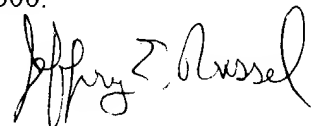
1. The proposed amendment after final rejection filed July 26, 2004 raises new issues which would require further consideration and/or search. The scope of the disorders and/or diseases being claimed in proposed claims 1 and 24 is new, and would necessitate further consideration and search because compounds outside the scope of the elected species would have to be searched. See also MPEP 803.02, last paragraph.
2. Claims 22 and 23 are deemed to be properly withdrawn from consideration. This is because claims 22 and 23 do not generically embrace the elected species. The issue of what claims are withdrawn after an election of species requirement is not dependent upon whether the claims are embraced by Applicants' most generic claim, but rather depends upon whether the claims embrace the elected species. The examiner agrees that once a generic claim is indicated as allowable, then if claims 22 and 23 are properly dependent upon the allowed generic claim, claims 22 and 23 will be re-joined with the allowed generic claim and examined therewith.
3. The proposed amendment to claim 8 would overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in section 2 of the final Office action.
4. In proposed claim 11, the status identifier is incorrect, and should have been "(Previously presented)".
5. With respect to proposed claim 24 and the WO Patent Application 98/25644, the claim would still be rejected over the reference for the reasons of record. The phrase "consisting essentially of" in the proposed claim excludes only those method steps which would materially alter the basic and novel characteristics of Applicant's invention. See MPEP 2111.03. Applicant has not demonstrated that co-administration of GLP-2, as required by the WO Patent Application '644, would materially alter the basic and novel characteristics of Applicant's invention. It is

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irrelevant to the interpretation of this phrase as to whether the additional method steps or components of the prior art, i.e. the GLP-2 co-administration of the WO Patent Application '644, are necessary for the purposes of the prior art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 30, 2004